

Heart-Related Multiple Chronic Conditions in Primary Care: Behavioral Technology

NCT03387735

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**University of Wisconsin-Madison  
and Medical University of South Carolina  
Consent to Participate in Research  
and  
Authorization to Use Protected Health Information for Research**

**Study Title for Participants:** ElderTree for Managing Chronic Health Conditions

**Formal Study Title:** Heart-Related Multiple Chronic Conditions in Primary Care: Behavioral Technology

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**Where Lead Researcher works:** Center for Health Enhancement Systems Studies (CHESS), College of Engineering, University of Wisconsin-Madison

**Invitation**

We invite you to take part in a research study for ElderTree, a website application to help older adults with Multiple Chronic Health Conditions (MCC) better manage their own health outcomes. ElderTree is designed to increase self-management, health tracking, and communication with others with similar health issues and with your primary care physician. We are inviting you because you are 65 years or older, have been treated in your clinic for the last 18 months, and have at least 3 chronic health conditions.

The purpose of this consent and authorization form is to give you the information you need to decide whether to be in the study. It also explains how health information will be used for this study and requests your authorization (permission) to use your health information. Ask questions about anything in this form that is not clear. If you want to talk to your family and friends before making your decision, you can. When we have answered all your questions, you can decide if you want to be in the study. This process is called “informed consent.”

**Why are we doing this study?**

The purpose of this study is to test ElderTree to see if it will help patients with multiple chronic health conditions better manage their own health care. This research is being done because multiple chronic health conditions are common among people aged 65 and older. Multiple chronic conditions can lower quality of life, make health treatment and management complicated and expensive for the patient, and can contribute to feelings of isolation and loneliness.

This study is being done at the University of Wisconsin-Madison (UW-Madison) and the Medical University of South Carolina (MUSC), in partnership with primary care clinics in Wisconsin and South Carolina. A total of about 330 people will participate in this study.

Funding for this study is provided by the National Institutes of Health.

**What will I do in this study?**

Participation in the study is completely voluntary and will last a total of 18 months. All activities will take place in your home or in a place of your choosing.

After you join the study, you will be randomly put in one of two groups, decided by chance (like the flip of a coin).

**Group 1. Control Group:** you will receive a computer and an internet hotspot, if you don't already have one, and given access to helpful websites such as the CDC website, FamilyDoctor.org (American Academy of Family Physicians), HealthFinder (DHS), and NIH SeniorHealth.

**Group 2. ElderTree Group:** you will receive a computer and an internet hotspot, if you don't already have one, and given access to the ElderTree website for 12 months.

If you choose to participate you will be asked to:

- Give your primary care physician permission to share lab test results from your medical records with the study team.
- Complete a survey at the beginning of the study. The survey will take 20-30 minutes and will ask about your demographics, quality of life, symptom management, pain, medication adherence, and health care utilization.
- Complete surveys at 6, 12 and 18 months. The surveys will be mailed to you to complete and return to us in a self-addressed stamped envelope. You may skip any question on the survey that you do not wish to answer. The surveys will take 20-30 minutes each and will ask about your quality of life, symptom management, pain, medication, and health care utilization. If we do not receive the completed survey in the mail, we may call to remind you to complete it.
- Complete weekly check-ins that will ask you how you are doing, specifically your mood, sleep, eating, and level of social interactions. These questions will be sent to you on the ElderTree system and will take about 2-4 minutes to complete. All questions are voluntary. You are free to refuse to answer any questions you are uncomfortable with. The information you share on ElderTree will be shared with your health care provider and will also be sent to you to share with other health care providers so they can provide you support where it is most needed.

In addition, if you are in the ElderTree group we ask that you:

- allow the research team to collect information on how you use the ElderTree site.
- participate in on-line discussions
- identify and track a health goal
- complete surveys on ElderTree each week

Important things to note:

- There is no financial cost to you to participate in this study. The only cost to you is your time spent using the technology and completing surveys
- If anything happens to the equipment we provide to you, you are not responsible if it is stolen or broken. However, we will not be able to repair or replace it.
- At the end of the study the computer is yours to keep, however the internet hotspot will need to be returned to the study team.

### **How we will use your protected health information (PHI)**

Protected health information, also called PHI, is information about your physical or mental health that includes your name or other information that can identify you, like your date of birth or medical record number. For this study, we will use the following kinds of PHI:

- Name, address, and phone number
- Things you tell the research team about your health
- Information will be collected from medical records at UW Health, including information currently in your medical records as well as information added to your medical records during the course of this study. The data we will obtain from your medical records are:
  - Systolic and diastolic BP
  - Weight
  - BMI
  - HDL/LDL
  - HbA1C
  - pain score
  - health care utilization: number of ER visits, urgent care visits, PC visits and specialty care visits
  - anxiety
  - depression
  - osteoporosis
  - cancer

**How long will I be in this study?**

You will be part of the study for 18 months. You will have internet access for 12 of the 18 months. You will complete 4 surveys during this time; each survey is expected to take 20-30 minutes.

If you are assigned to the ElderTree group, you will be asked to spend an hour each week participating in ElderTree activities.

**How is being in this study different from my regular health care?**

This study is separate from your regular health care. If you decide to participate in the study, it will not change your regular health care in any way.

People with multiple chronic conditions have regular visits with their primary care physician that involve lab tests and medication monitoring. If you participate in this study, you will continue to have these visits as you normally would. For the study, we will ask you to answer surveys about how your conditions affects your behavior and quality of life. You may skip any questions you do not wish to answer.

**Do I have to be in the study? What if I say “yes” now and change my mind later?**

You do not have to be in this study. Taking part in this research is voluntary. This means that you decide if you want to be in the study. If you decide to participate, you can change your mind and leave the study at any time.

Let the researchers know if you choose to leave the study.

If you decide not to take part in the study, or if you choose to leave the study, your choice will not affect any treatment or relationship you have with your healthcare provider, or any services you receive from them. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

Your permission for researchers to use your protected health information (PHI) will last until the research study is done. However:

- You can choose to take back your permission for researchers to use your health information. You can do this at any time before or during your participation in the research.
- If you take back your permission, information that was already collected may still be used and shared with others, but the researchers will no longer be able to collect NEW information about you.
- If you take back your permission, you will not be able to take part in the research study, therefore your access to the ElderTree application and internet access will be ended.

To take back your permission, you will need to tell the researchers by writing to the study coordinator Klaren Pe-Romashko at CHESS, 4155A Mechanical Engineering, 1513 University Avenue, 53706 or emailing kspe@wisc.edu or calling 608-263-3322.

**What are the risks?**

- There is a risk that your information could become known to someone not involved in this study, which might make you uncomfortable. We take many steps to protect your confidentiality and prevent this from happening.
- ElderTree could give you wrong information. However, a panel of experts reviews the information before it is added to ElderTree.
- You could get wrong information from the Internet. However, we will provide you with simple tips to help you identify more trustworthy sites.
- It is possible you could get upset from a posting in the online discussion group. The study team will routinely monitor discussion groups and appropriate action will be taken if a questionable post has been made online and/or if posts may put an individual at risk.
- You may feel a sense of loss when internet access is stopped.
- Participants will be asked personal questions related to past or current behaviors and experiences that could produce emotional stress or sadness.
- We will be collecting information on how the application is used and may discover behavior that raises concern about harm to yourself or others. If we see anything that suggests imminent and urgent risk of harm, we will contact appropriate others to intervene (e.g., community mental health center and/or police)
- The surveys you will complete in this study ask about symptoms of emotional distress such as depression or anxiety. We are using the survey only for research, not to diagnose mental health issues. If you are experiencing emotional distress, you should contact your physician or other health care provider, such as a mental health professional. Information you enter into ElderTree can be viewed by your primary care provider, via the ElderTree application, regardless if they are enrolled in the study as staff subjects. The information you enter into ElderTree can also be viewed by the UW research coordinators. The purpose of this information sharing is to guide your health care team in how best to ensure your health and support you. Your primary care physician will see a graph that charts your weekly scores related to the quality of your sleeping, nutrition, physical activity, memory, falls, moods, balance, pain, medication adherence and quality time spent with others. This information will not be entered into your medical record.

**Will being in this study help me in any way?**

Being in this study may help you learn how to better manage your health conditions and better communicate with your physician. However, we cannot promise this will happen. Even if the study does not help you directly, your participation in this study may help other people in the future as it will help us learn more about supporting older adults with several chronic health conditions.

**Will being in this study cost me anything?**

There will be no cost to you for the activities that are part of this research study.

**Will I be paid or receive anything for being in this study?**

We will pay you \$10 for completing each of the 4 surveys, for a total of \$40. Payment will be mailed to you when we receive your completed survey. If you choose to leave the study early, you will receive payment for the surveys completed, but not for future surveys.

The laptop will be yours to keep at the end of the study if you have completed all of the surveys.

**How will researchers keep my research information confidential?**

We have strict rules to protect your personal information and protected health information (PHI). We will limit who has access to your name, address, phone number, and other information that can identify you. We will also store this information securely. We may publish and present what we learn from this study, but none of this information will identify you directly.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States federal or state government agency sponsoring the project and that will be used for auditing or program evaluation of agency funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

However, we cannot promise complete confidentiality. Federal or state laws may require us to show information to university or government officials responsible for monitoring the study. If the researchers decide you are in danger or suspect abuse or neglect in the home your confidentiality will be broken as they will be required by law to report it to your state Department of Human and Social Services.

**Who at UW-Madison can use my information?**

- Members of the research team
- Offices and committees responsible for the oversight of research

**Who outside the UW-Madison may receive my information?**

- U.S. Office for Human Research Protections
- The study sponsor, National Institutes for Health
- Collaborating researchers outside UW-Madison, including researchers at the Medical University of South Carolina research team

**Will information from this study go in my medical record?**

None of the information we collect for this study will be put in your medical record.

Authorizing the research team to use your PHI means that we can release it only to the people or groups listed above, and only for the purposes described in this form.

Also, if ALL information that can identify you is removed from the health information collected in this study, then it is no longer PHI and this authorization will no longer limit how the remaining information can be used. This means the information could be used or shared for reasons other than the ones described in this form, such as a research study about another kind of disease. It also means that the information could be shared with researchers working at institutions that are not listed above.

**Conflict of Interest**

A member of this research team has a personal interest in or might profit financially from the results of this study. This is called a “conflict of interest.” Dr. David Gustafson, the principal investigator is part owner of a company called CHESS Mobile Health, Inc. The University of Wisconsin-Madison has rules to manage conflicts of interest that help protect study participants and the quality of the data collected. One way UW-Madison manages conflicts is to limit the role that a researcher with a conflict can have on a study, such as not allowing a person with a conflict to obtain informed consent or recruit potential subjects. The conflict of interest may affect whether you want to take part in this study.



Study #: 2017-0849. UW Patient Consent Form  
Version: 8/28/2018

**ClinicalTrials.gov**

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

**What if I have questions?**

If you have questions about this research, please contact the study coordinator, Klaren Pe-Romashko at CHESS, 4155A Mechanical Engineering, 1513 University Avenue, 53706 or email [kspe@wisc.edu](mailto:kspe@wisc.edu) or call 608-263-3322.

If you have any questions about your rights as a research subject or have complaints about the research study or study team, contact UW Health Patient Relations at 608-263-8009. The Patient Relations Representatives work with research subjects to address concerns about research participation and assist in resolving problems.

**Agreement to participate in the research study**

You do not have to sign this form. If you refuse to sign, however, you cannot take part in this research study.

If you sign the line below, it means that:

- You have read this consent and authorization form.
- You have had a chance to ask questions about the research study, and the research team has answered your questions.
- You want to be in this study.
- You give authorization for your protected health information to be used and shared as described in this form.

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Printed Name of [Subject/Participant]

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Signature of Research [Subject/Participant]

Date

Name of your Primary Care Physician: \_\_\_\_\_

Are you willing to be contacted about participating in additional phone interviews conducted by a UW researcher? Please circle one.

Yes

No

Are you willing to be contacted about participating in an in-person focus group conducted by a UW researcher? Please circle one.

Yes

No

\_\_\_\_\_  
Initials

I give my permission to be quoted directly in publications. I understand my name will not be used in the quote.

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Signature of Person Obtaining Consent and Authorization

Date

**\*\*You will receive a copy of this form\*\***